MAY 12 2000

510(k) SUMMARY

Submitter's Name: Humagen Fertility Diagnostics, Inc.

Address: 2400 Hunter's Way
Charlottesville, VA 22911

Telephone #: (804) 979-4000

FAX #: (804) 295-5912

Contact person: Cindy Showalter

Date summary prepared: February 15, 2000

Device name:

Classification name: Assisted reproduction microtools (per CFR# 884.6130)

Common/Usual name: Pasteur pipets used for in vitro fertilization

Proprietary names: None

Substantial Equivalence:

Substantial equivalence is being supported by the Federal Register Notice Final Rule entitled "Obstetric and Gynecologic Devices; Reclassification and Classification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures. This equivalence is supported by the SUMMARY statement:

> Upon the effective date, the Federal Register document may be cited in the absence of an existing predicate device which would be used to support substantial equivalence.

Pasteur pipets historically have been a common piece of labware used in this procedure. The proposed devices are differentiated from those currently being used only by being provided to the user pre-packaged and sterile.

Description of Device:

The disposable Pasteur pipets are made of borosilicate glass. The pipets are pre-manufactured and purchased from a supplier, and are available in 5 ¾" and 9" lengths. Humagen prepares the pipets by documented procedures to eliminate endotoxins. The pipets are then packaged 3 to an individually labeled, self-sealing package which has been tested to ensure integrity as well as a microbial barrier. The pipets are then sterilized by dry heat in this individual packaging. The Pasteur pipets are then placed in a larger box containing 40 individual packages consisting of 3 pipets each.

Intended use statement:

Pasteur pipets are commonly used in the IVF laboratory for general pipetting purposes. These include: 1) transferring tissue culture media or other liquids from one container to another, 2) moving cells or embryos from one container to another, and 3) when pulled over a flame to a finer tip, may be used to remove cumulus cells from ova prior to *in vitro* fertilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Ms. Cindy Showalter
Quality Assurance Manager
Humagen Fertility Diagnostics, Inc.
2400 Hunter's Way
Charlottesville, VA 22911

Re: K000915
Prepared Pasteur Pipets
Dated: March 17, 2000
Received: March 22, 2000
Regulatory Class: II
21 CFR §884.6160/Procode: 85 MQK

Dear Ms. Showalter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) NUMBER (IF KNOWN): K000915

DEVICE NAME: PREPARED PASTEUR PIPETS

INDICATIONS FOR USE:

Pasteur pipets are a general laboratory pipette to be used anytime there is a need to move fluid or cells. They may also be used to "denude" ova prior to an IVF procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000915